

REMARKS

The Official Action of January 19, 2007, and the prior art cited and applied therein have been carefully reviewed. The claims in the application are now claims 1-9 and 13-17, and these claims define novel and unobvious subject matter warranting their allowance. Applicants therefore respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 4-6 have been rejected under the first paragraph of §112. The rejection is respectfully traversed.

The rejection maintains that claims 4-6 are so broad as to cover prevention of any digestive disease, and that the specification does not enable those skilled in the art to practice the invention so broadly. While applicants do not agree because those skilled in the present art could practice the inventions as broadly as originally claimed without any experimentation at all, or with at most only routine experimentation, nevertheless the preambles of claims 4-6 have now been amended based on the examples of the present application, especially examples 13-15.

Withdrawal of the rejection is in order and is respectfully requested.

Some additional amendments have been made in claims 4-9 to better conform with U.S. practice. These claims are composition claims, so they have been amended to recite the presence of a pharmaceutically acceptable carrier or excipient, support being found at page 7 of the specification. The expression "pharmaceutically acceptable carrier or excipient" is intended to encompass any kind of pharmaceutically acceptable agent used in conjunction with active or effective ingredients, including sterilized liquid agents and suspending agents, physiologically recognizable vehicles, carriers, fillers, integrate agents, stabilizers, flavors, sweeteners, vehicles, aguvants, lubricants, etc.

New claims 16 and 17 have been added, based on claims already present, with further support being found at page 7, lines 14-16. These claims are patentable for the same reasons as the other claims, as explained below.

Claims 10-12 have been rejected under the second paragraph of §112. These claims have now been deleted without prejudice, applicants reserving their rights without penalty to reintroduce such claims at a later date, such as in a continuing application, if it is later deemed desirable or necessary, applicants in such a case relying on §§120 and 119. As such claims have been cancelled above without prejudice, applicants need not address this rejection at the present time.

Claims 1-15 have been rejected under §102 as anticipated by Sakuma U.S. patent application publication 2003/0161841 (Sakuma). This rejection is respectfully traversed.

Sakuma discloses preventive and therapeutic agents against the HIV virus and pathogenic bacteria among which is mentioned *Helicobacter pylori*, paragraph [0078]. As to what these therapeutic agents are, the PTO relies on paragraph [0008] which refers to extracts from Kabanoanatake [*Fuscopia oblique* Aoshima]. This paragraph further states as follows:

From having sought further benefits on the basis of these observations, it was confirmed that the Kabanoanatake extracts contain great quantities of LPS (Lipopolysaccharide) and pseudo-humic acid (humins like polyphenol complex) which has a high content of methoxyl groups including also monolignin. From there, it was found that the Kabanoanatake extracts are effective in preventing cancers, microbe-related to syndromes such as HIV, ATL (adult T cell leukemia virus) and pathogenic bacteria, especially *Escherichia coli* 00157.

The PTO apparently concludes that the "humins like polyphenol complex" corresponds with applicants' proanthocyanidine, although there is no evidence that this is so.

Applicants respectfully maintain that Sakuma does not disclose the proanthocyanidine of the present invention which is characterized (e.g. claim 1) as having the "effect of attenuating a vacuolating toxin produced by *Helicobacter pylori*."

Further in this regard, it may be pointed out that applicants' proanthocyanidine is derived from hop, hop bract or

apple (not "Kabanoanatake"), particularly immature apple (see, for example, applicants' specification at page 4, lines 25 et seq; page 3, lines 17-19 and 33-35; and page 4, lines 8-10, as well as the examples). There is no such disclosure of a polyphenol or proanthocyanidine in Sakuma, it being noted that reference to "apple" in paragraph [0147] relates to a food to which the extract may be added and not a source of the extract, and reference to "hops" in paragraph [0148] relates to a substitute for hops rather than a source of the extract.

Another factor supporting the conclusion that applicants' claimed proanthocyanidine is not anticipated by Sakuma, i.e. it is novel, is that fact that Sakuma discloses an extract which has activity against the bacteria itself, whereas applicants' proanthocyanidines are active against the **vacuolating toxin** produced by *Helicobacter pylori*. It makes sense that Sakuma's extracts are different as they have different activity, i.e. activity against pathogens rather than toxins, and because their source is different, the Kabanoanatake source of the Sakuma extract being a type of mushroom, i.e. a bio-species which is very different from apples, hops and hop bracts.

The rejection, while not stating so, seems to be based on a believed inherency, i.e. that the extracts are inherently the same. Insofar as anticipation is concerned, it should be agreed that it is generally improper to base an anticipation rejection on what a reference fails to disclose, i.e. silence in

a reference, the only exception being a clear case of inherency. But inherency cannot be presumed. See *In re Brink*, 164 USPQ 247, 249, where the Court stated:

Absent a showing [by the PTO] of some **reasonable certainty** of inherency, the rejection... under 35 USC 102 must fail. [emphasis added].

Also see *Ex parte Cyba*, 155 USPQ 756, 757 (1967) and *In re Oelrich*, 212 USPQ 323, 326 (1981), the former case holding that "inherency must be certain" and the latter case holding that inherency must be "inevitable", and not established by probabilities or possibilities.

A more recent case is *Ex parte Levy*, 17 USPQ2d 1461, 1463-64 (BPAI) wherein the Board stated as follows:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art. [citations omitted; italics in original].

Also see *Crown Operations International v. Solutia*, 62 USPQ2d 1917, 1923 (Fed. Cir. 2002), where the Court repeated, "Inherency 'may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'"

Accordingly, applicants respectfully maintain that not only is inherency not inevitable or reasonably certain in the present case, but the fact of different activities and different

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sources makes all the more clear that applicants' extracts are quite different from those of Sakuma.


There is no anticipation. Withdrawal of the rejection is in order and is respectfully requested.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration and early formal allowance are respectfully requested.

Respectfully submitted,

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